GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:525
ANSWERED ON:18.11.2016
Medical Devices Regulations
Patel Shri Devji Mansingram

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether various organizations and associations have raised certain objections on the second draft of the Medical Devices Regulations notified recently;

(b) if so, the details thereof; and

(c) the corrective steps taken by the Government to boost manufacturing of medical devices in the country?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): The draft Medical Devices Rules have been e-gazetted on 17.10.2016 for inviting comments and suggestion from all stakeholders. Till now, comments and suggestion have been received from some organization. The last date for receipt of comments was 16.11.2016

(c): Availability of a transparent, objective and predictable regulator y framework for medical devices is a pre-requisite for boosting domestic manufacture of medical devices. Draft Medical Devices Rules have been framed keeping this in view. Further, the Government is providing some facilities for medical devices parks such as Andhra Pradesh Med Tech Zone (AMTZ) to set
Up common facilities.